

IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the)	
Use and Benefit of Herself and the Next Kin of)	
Richard Smith, Deceased,)	
)	
Plaintiff,)	Civil No. 3:05-0444
)	Judge Aleta A. Trauger
v.)	(Dist. Of MA No.
)	1:05-cv-11515PBS)
PFIZER, INC., <i>et al.</i> ,)	
)	
Defendants.)	

**DEFENDANTS' OBJECTIONS TO THE PROPOSED STATEMENT OF
PLAINTIFF'S EXPERT RONALD WM. MARIS, PH.D.**

Pursuant to the Court's Scheduling Order of April 30, 2010, as amended orally due to flooding in Nashville, Defendants, Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer") herein submit their objections to the expert witness statement proffered by Plaintiff's expert, Ronald Wm. Maris, Ph.D, who is designated to testify about causation issues. These objections are in addition to, and without waiving, any applicable objections made in connection with Defendants' motions in limine that were filed and ruled upon by the Court.¹

¹ Defendants moved *in limine* to exclude the specific causation testimony of Dr. Maris on the grounds that it was unreliable and inadmissible because (1) he did not and cannot rule out alternative causes of Mr. Smith's suicide; (2) he cannot identify a "hallmark" for suicides caused by Neurontin; (3) he relies instead on speculation and logical fallacy to differentiate a suicide caused by Neurontin from a suicide caused by any number of established suicide risk factors; and (4) he uses unreliable methods (more specifically, he did not use the psychological autopsy method reliably in this case and created and produced a new suicide model for the first time at deposition that is unreliable). The Court denied the motion *in limine*, and these objections seek not to rehash the same issues raised in the motion, although Defendants are not waiving any arguments raised in the motion *in limine*.

TESTIMONY	OBJECTION
Unnumbered Introductory Paragraph – “You may be wondering if I am related to former Yankee and St. Louis baseball player, Roger Maris. The short answer is ‘yes,’ distantly. He and I were the same age and I went to the University of Illinois on a track and basketball scholarship.”	<ul style="list-style-type: none"> Irrelevant (FRE 401, 402)
¶ 1, n.1 – “Neurontin affects the neurotransmitter Serotonin, which can make a person more suicidal”	<ul style="list-style-type: none"> Foundation, witness lacks knowledge, skill, experience, training, or education sufficient to render opinion (FRE 702)²
All of ¶ 2, entitled “Prescription Drugs Can Cause Suicides.” ³	<ul style="list-style-type: none"> Irrelevant (FRE 401, 402) Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403) Improper propensity evidence (FRE 404(b))⁴ Not helpful to trier of fact (FRE 702) Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))⁵

² Dr. Maris conceded at deposition that (1) he is not an expert in neuropharmacology (9:16-19); (2) he is relying on Dr. Trimble and Dr. Kruszewski for his mechanism opinion (182:2-17); (3) he did not do anything to test the theories of Dr. Trimble and Dr. Kruszewski about the purported mechanism of Neurontin (152:18-23); and (4) he is not competent to test the theories of Trimble and Kruszewski, or to answer questions regarding Neurontin’s mechanism of action (162:18-25; 163:24-164:21; 179:11-20; 193:2-21; 201:10-15).

³ In the event the Court strikes all of ¶ 2, the remaining objections to individual statements within the paragraph need not be addressed.

⁴ See also, e.g., *Rye v. Black & Decker Mfg. Co.*, 889 F.2d 100, 102-03 (6th Cir. 1989) (district court did not err in excluding evidence of 15 prior Black & Decker saw injuries because prior incidents not shown to be substantially similar to incident at issue, and excludable separately on Rule 403 grounds).

⁵ This opinion is not one of the seven opinions set forth in Dr. Maris’s expert report, a revised version of which was produced after his deposition. See also, e.g., *Roberts v. Galen of Va., Inc.*, 325 F.3d 776, 782 (6th Cir. 2003) (“Federal Rule of Civil Procedure 37(c)(1) requires

<p>¶ 2 – “In the past 10 years, it has become clear that many prescription drugs can cause suicides.”</p>	<ul style="list-style-type: none"> • Irrelevant (FRE 401, 402) • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403) • Improper propensity evidence (FRE 404(b)) • Not helpful to trier of fact (FRE 702) • Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))
<p>¶ 2 – “This research group concluded that anti-depressant drugs were linked to suicides in adolescents and children.”</p>	<ul style="list-style-type: none"> • Irrelevant (FRE 401, 402) • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403) • Improper propensity evidence (FRE 404(b)) • Not helpful to trier of fact (FRE 702) • Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))
<p>¶ 2 – “The FDA adopted these conclusions and anti-depressants today carry a suicide warning.”</p>	<ul style="list-style-type: none"> • Irrelevant (FRE 401, 402, 407) • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403) • Improper propensity evidence (FRE 404(b))

absolute compliance with Rule 26(a), that is, it mandates that a trial court punish a party for discovery violations in connection with Rule 26 unless the violation was harmless or is substantially justified.”) (internal quotation marks and citation omitted).

	<ul style="list-style-type: none"> • Not helpful to trier of fact (FRE 702) • Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))
¶ 2 – “Given this relatively recent data, it is clear that some prescription drugs are also risk factors for suicide.”	<ul style="list-style-type: none"> • Irrelevant (FRE 401, 402) • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403) • Improper propensity evidence (FRE 404(b)) • Not helpful to trier of fact (FRE 702) • Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))
The heading of ¶ 3, entitled “Neurontin is a Powerful Mood-Altering Drug.” ⁶	<ul style="list-style-type: none"> • The heading is argumentative and not supported by the body of the paragraph • Foundation, insufficient facts or data, unreliable principles and methods (FRE 702) • Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)⁷
¶ 3 – “The drug was designed to work by changing the levels of neurotransmitters in the brain.”	<ul style="list-style-type: none"> • Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)⁸
All of ¶ 4, entitled “FDA Concluded in 2008 that Neurontin Was Linked to Suicides.”	<ul style="list-style-type: none"> • Misstates facts • Hearsay (FRE 802)

⁶ In the event the Court strikes all of ¶ 3, the remaining objections to individual statements within the paragraph need not be addressed.

⁷ See *supra* note 2.

⁸ See *supra* note 2.

	<ul style="list-style-type: none"> Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)⁹
Exhibit 3849 (referenced in ¶ 4)	<ul style="list-style-type: none"> Irrelevant (FRE 401, 402, 407) Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403) New Warning Rule of Completeness
Exhibit 2018 (referenced in ¶ 5)	<ul style="list-style-type: none"> Irrelevant (401, 402, 407) Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403) Hearsay (FRE 802)
All of ¶ 6, entitled “Neurontin Can Cause Suicides.”	<ul style="list-style-type: none"> Foundation, insufficient facts or data, unreliable principles and methods (FRE 702) Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702) Hearsay, hearsay-within-hearsay (FRE 802, 805) Misstates the facts
Exhibit 460 (referenced in ¶ 6)	<ul style="list-style-type: none"> Hearsay, hearsay-within-hearsay (FRE 802, 805)
¶ 6 – Testimony that study discussed in Exhibit	<ul style="list-style-type: none"> Foundation, insufficient facts or data,

⁹ During his deposition Dr. Maris conceded that (1) the FDA 2008 analysis pooled data from 11 different anti-epileptic drugs, including Neurontin; (2) there was no statistically significant association between Neurontin and suicidal behavior or ideation (263:7-17, 267:3-21); and (3) based on the FDA’s analysis, he cannot conclude that Neurontin causes suicide (280:3-6).

5869 “basically replicated the findings of the FDA that all anti-epileptic drugs generally increase the risk of suicide.”	<p>unreliable principles and methods, given that study did not find statistically significant increase in suicide risk for Neurontin (FRE 702)</p> <ul style="list-style-type: none"> • Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702) • Misstates facts
Exhibit 5870 (referenced in ¶ 6) and discussion related to it	<ul style="list-style-type: none"> • Hearsay, hearsay-within-hearsay (FRE 802, 805) • Foundation, insufficient facts or data, unreliable principles and methods, given that is only an exploratory study and does not have an untreated randomized control group (FRE 702) • Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)
¶ 6 – “Neurontin (or gabapentin) increases a neurotransmitter in the brain called GABA. This increase in GABA, in turn, decreases brain chemicals (most notably monoamines like serotonin and norepinephrine). A decrease in serotonin (and serotonergic dysfunction in general) has been linked to suicidal behavior, especially for modern anti-depressantt drugs (such as the 9 studied for the FDA and Columbia University). This interaction of GABA and serotonin is one likely explanation of the link between Nuerontin and suicide.”	<ul style="list-style-type: none"> • Foundation, insufficient facts or data, unreliable principles and methods (FRE 702) • Foundation, witness lacks knowledge, skill, experience, training, or education sufficient to render opinion (FRE 702)¹⁰
All of ¶ 9, entitled “Richard Smith Was Taking Neurontin When He Committed Suicide.”	<ul style="list-style-type: none"> • Not appropriate expert testimony because issue of whether Richard Smith was actually taking Neurontin is not outside the scope of knowledge and experience of the jury in weighing the evidence (FRE 702)
¶ 10 – “Significantly, several of these risk	<ul style="list-style-type: none"> • Foundation, insufficient facts or data,

¹⁰ See *supra* note 2.

factors (depression, suicidal thoughts, and hopelessness) were triggered and/or made worse by Neurontin usage.”	<p>unreliable principles and methods (FRE 702)</p> <ul style="list-style-type: none"> Foundation, insufficient bases for opinion (FRE 703)
¶ 10 – “Roughly speaking, Richard Smith was a 5 on a 10 point scale for suicide risk.”	<ul style="list-style-type: none"> Foundation, insufficient facts or data, unreliable principles and methods (FRE 702) Foundation, insufficient bases for opinion (FRE 703)
¶ 10 – “Richard Smith also possessed numerous personal characteristics that are protective from suicide.”	<ul style="list-style-type: none"> Foundation, insufficient facts or data, unreliable principles and methods (FRE 702) Foundation, insufficient bases for opinion (FRE 703)¹¹
¶ 11 – “This change in behavior or character is typical of drug-induced suicides.”	<ul style="list-style-type: none"> Irrelevant (FRE 401, 402) Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403) Improper propensity evidence (FRE 404(b)) Not helpful to trier of fact (FRE 702)
¶ 11 – “That is, Neurontin made Richard’s depression much worse.”	<ul style="list-style-type: none"> Foundation, insufficient facts or data, unreliable principles and methods (FRE 702) Foundation, insufficient bases for opinion (FRE 703)
All of ¶ 13, entitled “Neurontin was a Substantial Contributing Factor in or Cause of Richard Smith’s Suicide.” ¹²	<ul style="list-style-type: none"> Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)

¹¹ Dr. Maris testified at deposition that the protective factor that Mr. Smith “was musical and life affirming” was “[p]robably not” supported by any peer-review published literature, and “so probably that’s a weak one.” (806:3-9)

	<p>702)</p> <ul style="list-style-type: none"> Foundation, insufficient bases for opinion (FRE 703)
<p>¶ 13 – “As a result of this process, commonly referred to as a ‘<i>differential diagnosis</i>,’ I conclude that Neurontin was a significant contributing factor in or cause of Richard Smith’s suicide. Thus, in terms of differential diagnosis, Richard Smith’s taking Neurontin was the <i>coup de grace</i> which caused his suicide. It was the ‘trigger’ or acute factor that potentiated, induced, or made worse the other suicide risk factors. I believe that gabapentin pushed Richard Smith over the edge. He changed dramatically after taking Neurontin. Gabapentin was the trigger that destroyed Richard Smith’s considerable prior ability to cope with life’s problems and to fend off suicide.” (emphasis in original).</p>	<ul style="list-style-type: none"> Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)¹³ Foundation, insufficient bases for opinion (FRE 703)
<p>¶ 13, n.11 – “All that is required is that Neurontin was one of the causes of Richard Smith’s suicide, not the only cause. It was a necessary, but not sufficient condition for his suicide.”</p>	<ul style="list-style-type: none"> Improper expert testimony regarding legal standard (FRE 702)
<p>¶ 13, n.15 – “Smith likely did become more impulsive as a result of Neurontin causing a serotonergic dysfunction.”</p>	<ul style="list-style-type: none"> Foundation, insufficient facts or data, unreliable principles and methods (FRE 702) Foundation, witness lacks knowledge, skill, experience, training, or education sufficient to render opinion (FRE 702)¹⁴
<p>Unnumbered paragraph called “Disclosure” –</p>	<ul style="list-style-type: none"> Probative value substantially

¹² In the event the Court strikes all of ¶ 13, the remaining objections to individual statements within the paragraph need not be addressed.

¹³ Dr. Maris concedes in his testimony, at page 9 n.16, that he is using differential diagnosis – which is “[u]sually . . . used to ‘*rule-out*’ competing diagnoses” – to “rule in” suicide risk factors, including Neurontin. (emphasis in original). After conceding that applying the differential diagnosis approach in this unorthodox fashion is “somewhat complicated,” he states, without any support, that it is appropriate because suicide has many causes.

¹⁴ See *supra* note 2.

statement regarding the <i>types</i> of prescription drug cases in which he has testified, <i>i.e.</i> “in which Plaintiffs have alleged that a prescription psychiatric drug has caused a suicide.”	<p>outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403)</p> <ul style="list-style-type: none"> • Improper propensity evidence (FRE 404(b)) • Not helpful to trier of fact (FRE 702)
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Dated: May 12, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 12th day of May 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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